



U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

**PETITION UNDER 37 C.F.R. §§1.47(b)  
and 1.42**

Docket Number:  
1662/460041  
(formerly 11701/46007)

Application Number  
10/657,737

Filing Date  
September 3, 2003

Examiner  
Not Yet Assigned

Art Unit  
1614

Invention Title

PHARMACEUTICALLY ACCEPTABLE  
COMPOSITION COMPRISING AN AQUEOUS  
SOLUTION OF PACLITAXEL AND ALBUMIN

Inventor(s)  
KADIMA et al.

Address to:

Mail Stop Missing Parts  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

I hereby certify that this correspondence is being deposited  
with the United States Postal Service with sufficient postage  
as first class mail in an envelope addressed to:

Mail Stop Missing Parts, Commissioner for Patents, P.O.  
Box 1450, Alexandria, VA 22313-1450 on

Date: 5/19/04 Reg. No. 46,877

Signature: John Koy

SIR:

In response to the Notice to File Missing Parts of Application mailed November 26, 2003 Attorney for Applicants, Tenshuk A. KADIMA, Howard A. KAPLAN and Robert C. TUTTLE, hereby petitions the Commissioner under 37 C.F.R. §§1.47(b) and 1.42 hereby makes application for patent on behalf of and as agent for all the inventors. This petition includes proof of the pertinent facts showing that such action is necessary to preserve the rights of and to prevent irreparable damage to the parties.

The above-identified application is a continuation of U.S. Patent Application Serial No. 10/293,426, filed November 12, 2002, which is a continuation of Serial No. 09/947,420, filed September 5, 2001, which is a continuation of Serial No. 09/744,827 which is a 371 of PCT/US99/17179, filed July 29, 1999, which International Application claims the benefit of provisional application Serial No. 60/094,687, filed July 30, 1998.

The International Application was filed in the name of Novopharm Biotech, Inc. as Applicant for all designated States except the United States (Exhibit A). The inventors, Tenshuk KADIMA, Howard KAPLAN and Robert C. Tuttle, were listed as the applicants for

the United States. See attached copy of first page of published PCT application (Exhibit A).

Novopharm Biotech, Inc. assigned all of its rights in the international and national applications to Human RT in January 2001 (Exhibit B). A change of Applicant was filed with the International Bureau of WIPO on January 26, 2001 along with a Power of Attorney from Human RT appointing Dr. jur. Eva Somfai as Agent for Applicant (Exhibit C).

On January 26, 2001 Dr. Somfai (Human RT's foreign patent counsel) requested Kenyon & Kenyon (Human RT's U. S. patent counsel) to enter the national phase in the United States of PCT/US99/17179. Copies of January 26, 2001 order letter and Information Sheet for New Patent Application are attached (Exhibit D).

On January 26, 2001, Dr. Eva Somfai filed with the International Bureau a Rule 92bis letter requesting the addition of inventors, Lajos HEGEDUS, Krisztina KREMPELS, Krisztina PAAL and Gabor PETHO (Exhibit E).

On April 26, 2001 Kenyon & Kenyon sent a letter to Dr. Somfai sending copies of the application as filed, Declaration and Assignment forms for signing by the inventors three (3) originally-named inventors and a Power of Attorney form for signing by the Assignee, Human RT. Reminder letters were sent to Dr. Somfai on June 29, 2001 and August 30, 2001.

Despite many attempts, Kenyon & Kenyon was unable to contact the three inventors, as did the foreign patent counsel. On July 9, 2003, letters were sent by Kenyon & Kenyon to the three originally-named inventors by Registered Mail, Return Receipt Requested to their last known addresses as follows:

Tenshuk A. Kadima  
7 Woodington Bay  
Winnipeg, Manitoba, Canada R3P 1M6

Howard A. Kaplan  
18 Hillhouse Road  
Winnipeg, Manitoba, Canada R2V 2V9

Robert C. Tuttle  
782 Allegheny Drive  
Winnipeg, Manitoba, Canada R3T 5L2

The letters included copies of the application as filed and a Declaration form for signing and returning to Kenyon & Kenyon. Copies of the letters are attached (Exhibit F).

The letter addressed to Mr. Kadima was returned as unclaimed (Exhibit G).

The letter addressed to Mr. Tuttle was returned as "address incomplete" by the Canadian Postal Service (Exhibit H). The address used was the only address listed in the International Publication Number WO 00/06152 of PCT/US99/17179. We attempted to obtain address for the inventors through Lexis and Westlaw, but without success (Exhibit I).

We learned that one of the inventors, Dr. Howard Kaplan, was deceased. We contacted the attorney for the heir of Dr. Kaplan, Mr. Randall Gray of Pitblado Buchwald Asper, Manitoba, Canada. Mr. Gray referred us to Mr. Robert A. Watchman of that firm to resolve the matter. Mr. Gray, after discussing the matter with Mr. Kaplan's heir, Ms. Carole Grad, advised us by letter dated March 22, 2004 (Exhibit J) that Ms. Grad cannot sign the Declaration as worded, because she cannot declare that she has reviewed and understands the content of the specification, including the claims, among other things. (As the sister of the inventor, she does not have the scientific background to understand the invention.)

Accordingly, despite our diligent efforts to contact the originally-named inventors to obtain a signed Declaration, we were unable to obtain signatures from the three inventors. We therefore respectfully petition the Commissioner under 37 C.F.R. §§1.47(b) and 1.42 to make application for patent on behalf of and as agent for all the inventors and Human RT, assignee of PCT/US99/17179.

In view of the foregoing, Applicants respectfully request that this Petition be granted under these specific facts.

Applicants also respectfully request that the following four (4) additional inventors be added to this application:

After resolution of the 37 C.F.R. §§1.47(b) and 1.42 issues, Applicants will submit formal documents to add the above-mentioned additional four inventors to this application. These inventors (Lajos HEGEDUS, Krisztina KREMPELS, Krisztina PAAL and Gabor PETHO) have been previously included in the PCT (see Exhibit E).

A copy of the Notice to File Missing Parts of Application is also enclosed.

Applicants respectfully request a four-month extension of time to respond to the Notice to File Missing Parts of Nonprovisional Application, Filing Date Granted, for which a response period expiring on January 26, 2004 was set. The extended period expires on May 26, 2004.

The Commissioner is hereby authorized to charge payment of the following fees to the deposit account of Kenyon & Kenyon, No. 11-0600:

- 1) Basic Filing Fee of \$770.00;
- 2) Additional claims fee of \$1,106.00;
- 3) 37 C.F.R. §1.17(i) petition fee of \$130.00;
- 4) 37 C.F.R. § 1.136(a) extension fee of \$1,480.00; and
- 5) 37 C.F.R. § 1.116(e) surcharge of \$130.00.

The Commissioner is also authorized to charge any additional fees and credit any overpayment in connection with this communication to the deposit account of Kenyon & Kenyon, No. 11-0600. A copy of this communication is enclosed herewith for charging purposes.

Respectfully submitted,

Dated: 5/19/04

By Siu K. Lo  
Siu K. Lo  
Reg. No. 46,877

KENYON & KENYON  
One Broadway  
New York, New York 10004  
Tel: (212) 425-7200  
Fax: (212) 425-5288

CUSTOMER NUMBER 26646

2month

0007350

TLS

figur



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
10/657,737	09/03/2003	Tenshuk A. Kadima	1170146003 16621460041

26646  
KENYON & KENYON  
ONE BROADWAY  
NEW YORK, NY 10004

CONFIRMATION NO. 8923

FORMALITIES LETTER



\*OC000000012904910\*

Date Mailed: 06/08/2004

**NOTICE OF INCOMPLETE REPLY (NONPROVISIONAL)**

***Filing Date Granted***

The U.S. Patent and Trademark Office has received your reply on 05/21/2004 to the Notice to File Missing Parts (Notice) mailed 11/26/2003 and it has been entered into the nonprovisional application. The reply, however, does not include the following items required in the Notice.

The period of reply remains as set forth in the Notice. You may, however, obtain EXTENSIONS OF TIME under the provisions of 37 CFR 1.136 (a) accompanied by the appropriate fee (37 CFR 1.17(a)).

A complete reply must be timely filed to prevent ABANDONMENT of the above-identified application. Replies should be mailed to: Mail Stop Missing Parts, Commissioner for Patents, P.O. Box 1450, Alexandria VA 22313-1450.

- The signature of the following inventor(s) is missing from the oath or declaration:  
*Lajos Hegedus, Krisztina Krempels, Krisztina Paal, Gabor Petho*

Replies should be mailed to: Mail Stop Missing Parts  
Commissioner for Patents  
P.O. Box 1450  
Alexandria VA 22313-1450

*A copy of this notice **MUST** be returned with the reply.*

*H. Nguyen*  
Customer Service Center  
Initial Patent Examination Division (703) 308-1202

PART 1 - ATTORNEY/APPLICANT COPY



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>7</sup> : <b>A61K 31/337, 47/48, 47/42</b>		A1	(11) International Publication Number: <b>WO 00/06152</b>
			(43) International Publication Date: 10 February 2000 (10.02.00)
(21) International Application Number: <b>PCT/US99/17179</b>		(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).	
(22) International Filing Date: <b>29 July 1999 (29.07.99)</b>			
(30) Priority Data: <b>60/094,687 30 July 1998 (30.07.98) US</b>			
(71) Applicant (for all designated States except US): <b>NOVOPHARM BIOTECH, INC. [CA/CA]; 30 Novopharm Court, Toronto, Ontario M1B 2K9 (CA).</b>			
(72) Inventors; and			
(73) Inventors/Applicants (for US only): KADIMA, Tenshuk, A. [CA/CA]; 7 Woodington Bay, Winnipeg, Manitoba R3P 1M6 (CA). KAPLAN, Howard, A. [CA/CA]; 18 Hillhouse Road, Winnipeg, Manitoba R2V 2V9 (CA). TUTTLE, Robert, C. [US/CA]; 782 Allegheny Drive, Winnipeg, Manitoba R3T 5L2 (CA).		Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>	
(74) Agents: WU, Frank et al.; Morrison & Foerster LLP, 755 Page Mill Road, Palo Alto, CA 94304-1018 (US).			
(54) Title: PHARMACEUTICALLY ACCEPTABLE COMPOSITION COMPRISING AN AQUEOUS SOLUTION OF PACLITAXEL AND ALBUMIN			
(57) Abstract			
<p>An optically clear, pharmaceutically acceptable aqueous composition comprising paclitaxel or a derivative thereof, serum albumin and a pharmaceutically acceptable vehicle, wherein the composition comprises no more than 10 % organic solvent and has a pH of about 3.0 to about 4.8, is described. The serum albumin can be fatted or defatted, and the composition can optionally be lyophilized or optionally lyophilized and reconstituted. At least 70 % of the paclitaxel is bound to serum albumin, the ratio of paclitaxel to albumin is at least about 1:5, and the concentration of paclitaxel is at least about 25 µg/ml. Methods of making and using this composition are also provided.</p>			

# EXHIBIT B

## ASSIGNMENT

We, the undersigned Assignors

Novopharma Biotech Inc.  
30, Novopharma Court  
Toronto, Ontario, M1B 2K9 Canada

declare to have assigned our exclusive rights related to  
patent applications/protects outlined below on

Number ref.  
Táncsics M.u.02.  
N-2100 Gödöllő, Hungary

We also agree that this assignment be registered in the  
register of all international or national patent  
authorities.

Date of the patent application:

Number: PCT/US00/17179  
Title: "Pharmaceutically Acceptable Composition  
Comprising an Aqueous Solution of Paclitaxel  
and Albuterol"  
Priority: US 60/094607 30. July 1998

For the Assignor:

Date:  
Toronto, January 2001

For the Assignee:

Date:  
Gödöllő, January 2001

Signed by:

Capacity:

MICHAEL A. BYRNE  
CHIEF FINANCIAL OFFICER

Signed by:  
Lajos Hegedűs

Capacity:  
General manager

P-012

HUMAN  
SERUM PRODUCTION AND  
MEDICINE MANUFACTURING  
COMPANY LIMITED BY SHARES  
Táncsics M. u. 82.  
Gödöllő, Hungary  
2100

**SOMFAI & PARTNERS**  
H-1137 Budapest, Pozsonyi út 38  
Hungary

Special Delivery  
 Air mail  Registered  
 Express

Also by fax: 1 page(s) + 1

Nº: 00 41 22 740.14.35

Your letter:

Your ref: PCT/US99/17179

My ref: P-0112PCT

Please quote on all  
correspondence!

tel: (361)3495-298  
Fax:(361)3502-623

EXHIBIT C

INTERNATIONAL BUREAU OF WIPO  
34, chemin des Colombettes  
1211 Geneva 20  
SWITZERLAND

**URGENT!**

Budapest, 26. January 2001

F235,236/01 sé

<b>Re:</b>	<b>Registration of Assignment of Application</b>	
<b>PCT Application:</b>	PCT/US99/17179 29. 07. 1999	
<b>PCT Publication:</b>	WO 00/06152	10. 02. 2000
<b>Priority:</b>	30. 07. 1998	US 60/094687

1. The patent application in caption and all rights related thereto were assigned from the original PCT applicant Novopharm Biotech Inc., 30. Novopharm Court, Toronto, Ontario M1B 2K9, Canada.
2. Data of the present applicant and the signatory:

**Assignee:**  
HUMAN Rt.  
Táncsics út 82.  
H-2100 Gödöllő,  
Hungary

**Signatory:**  
Lajos HEGEDÜS  
managing director

3. Please register the above change according to PCT Rule 92/bis at your earliest convenience. The 30 months (Chapter II) period expires on 30. January 2001.
4. Please find enclosed the
  - Power of attorney signed by the new applicant  
appointing me to represent this application.

1 page \*

Thank you for your co-operation.

Respectfully

  
Dr. Eva Somfai  
patent attorney

Enclosure:

\*\* Fax and Mail: New Power of Attorney

Fax and Mail: Assignment Deed (follows on receipt)

P-0112

1/1

**MEGHATA MAZÁS**

Alulirott

**HUMAN RT;**  
Gödöllő, Hungary

ezennel meghatalmazzuk(zom) a  
**SOMFAI és TÁRSAI**  
Iparjogi Kft-t

Szabadalmi ügyvivő:  
Dr jur. Somfai Éva  
vegyészmérnök

hogy az  
US 60/094687  
PCT/US99/17179  
-ra alapított,

**Pharmaceutically Acceptable Composition  
Comprising an Aqueous Solution of  
Paclitaxel and Albumin**

című szabadalom és/vagy bejelentés

ügyben az illetékes hatóságok, bíróságok  
és hivatalok előtt teljes jogkörrel  
képviseljen.

Kelt/Date:

Név (Cég)/ Name (Firm):

**HUMAN RT.**

Cím/Address:

Táncsics M.u.82.  
H-2100 Gödöllő, Hungary

Aláírás(ok)/ Signature(s)::

L. Hegedűs  
Managing Director

Name and capacity of signatories

(no legalization is required)

P-0112

**POWER**

The undersigned

**HUMAN RT;**  
Gödöllő, Hungary

hereby appoint(s)  
**SOMFAI and PARTNERS**  
Industrial Rights Co. Ltd.

Patent Attorney:  
Dr jur. Eva Somfai  
eng. chem.  
concerning  
Patent and/or Application entitled

**Pharmaceutically Acceptable Composition  
Comprising an Aqueous Solution of Paclitaxel  
and Albumin**

Nº  
based on  
US 60/094687  
PCT/US99/17179

with full power of substitution and  
representation before the competent  
authorities, courts or offices.



11701 - 46001  
11 RT

SOMFAI & PARTNERS

Industrial Rights Co.Ltd.  
H-1137 Budapest  
Hungary

EXHIBIT D

Tel:(361)3495-298  
Fax:(361)3502-623

- Special Delivery
- Air mail  Registered
- Express
- Also by fax: 3+6 page(s)  
Nº: 00 1 212 425 5288  
Your letter: -

**URGENT!**  
**IMPORTANT!**

Law Office Kenyon & Kenyon  
One Broadway  
NEW YORK N.Y. 10004-1050  
U.S.A.  
X

Budapest, 26. January 2001

F231, 232/01kj

Attention of Mr. Steven J. Lee! and/or  
Mr. Patrick Bird!

**PRIVILEGED AND CONFIDENTIAL!**

Dear Colleagues,

Re: New Patent Application in US of  
HUMAN RT "NOVBIO" based on US 60/094687  
PCT/US99/17179

My ref: P-0112 US Please quote!  
Your ref: -

**NATIONAL APPLICATION TO BE FILED in US**

Please

- File a new patent application in Canada
- Enter the national phase of the PCT application in caption.

To be filed: On/before **30. January 2001**

- 12 months priority
- 20 months PCT
- 30 months PCT date.**

If it is possible to file within 31 months in your country please file timely before the due date.

Documents:	Now enclosed	Follows	Please inform	Remarks
Information sheet	X 2 pages			fax
PCT Publication cover	X 1 page			fax
Specification to be filed	see PCT publ			<input type="radio"/> 125 pages
Claims to be filed	see PCT publ			<input type="radio"/> 4 pages

Figures to be filed	see PCT publ			○ 28 pages
Abstract	see PCT publ			○ 1 page
Power		X		
Inventors decl.		X		
Transfer of rights		X		
Data of newly added inventors	X 1 page			○ ○
Priority document		X		
PCT Search Report				○
PCT Publication				○
Change of representation and owner filed at WIPO	X 1 page			
Completion of inventor's list filed at WIPO	X 2 pages			
Acceptance by WIPO			X	

- is already in your file (5934/2)
- ○ If you consider it would be better not to file this please
  - call me before filing any time between 9 and 19 our time
  - add the names when appropriate.

**Please indicate by return fax what else you need.** The outstanding documents will follow always with a copy of this letter.

We ask you to send the **filled-in Powers** and all other documents you need in the form **ready for signature**. Empty formulars will not be signed.

- The priority document was filed in English by the inventors Kadima Tenshuk, Kaplan Howard, Tuttle Robert C.
- The PCT application was filed by the assignor Novopharm Biotech, CA the prosecution was in English and the application was recently assigned. When writing this order letter the WIPO-registration of both the Assignment and completion of the list of inventors is still pending.

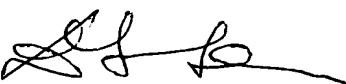
We await your debit notes in duplicate clearly indicating where and how you wish us to settle the same.

Please do not abandon this application if not expressly instructed to do so.

Please confirm receipt both of the faxed and the mail version of this order letter as well as the documents by fax.

Thanking you for your immediate attention and looking forward to have a good co-operation.

Sincerely yours



Dr. Eva Somfai  
chem. ing. patent attorney

Enclosure:

Fax:	6 page(s)
Air mail:	- page(s)
Spec. delivery	6 page(s)

## INFORMATION SHEET FOR NEW PATENT APPLICATION

**TITLE:** Pharmaceutically Acceptable Composition Comprising an Aqueous Solution of Paclitaxel and Albumin

**APPLICANT:** HUMAN RT  
Táncsics M.u.82.  
H-2100 Gödöllő, Hungary

**PRIORITY:** 30.07.1998 US 60/094687

**PCT APPLICATION:** PCT/US99/17179      **PRIORITY DATE:** 29.07.1999

**PCT PUBLICATION:** WO 00/06152      **PUBLICATION DATE:** 10.02.2000

**INVENTOR(S):** Kadima, Tenshuk  
Kaplan, Howard  
Tuttle, Robert C.  
Dr. Hegedűs, Lajos  
Dr. Krempels, Krisztina  
Dr. Pál, Krisztina  
Dr. Pethő, Gábor

|  
TO BE  
ADDED  
WHEN  
APPROPRIATE

To be filed: On/before 30. January 2001

- 12 months priority
- 20 months PCT
- 30 months PCT date.

If it is possible to file within 31 months in your country please file timely before the due date.

### ASSIGNMENTS:

- The priority application was filed by:  
Inventors Kadima, Kaplan, Tuttle (CA)  
all of Novopharm Biotech, CA.
- The PCT application was filed by:  
Novopharm Biotech, CA, except in the US where it was filed by inventors Kadima, Kaplan, Tuttle.
- The application was assigned on HUMAN RT., HU registration of the change was requested in the international phase on 26.01.2001

- The national application has to be filed in the name of HUMAN RT., HU alone.  
The assignment documents will follow as soon as available.
- Because important subject matter of the claimed invention was based on the invention of the four Hungarian inventors now appearing in the list of inventors - registration of completion of the inventor's list was requested on 26.01.2001 at the WIPO.

H-1137 Budapest, Pozsonyi út 8  
Hungary

Tel: (361)3495-298  
(361)3502-623

Special Delivery  
 Air mail  Registered  
 Express

X Also by fax: 1 page(s)

Nº: 00 41 22 740.14.35

Your letter:

Your ref: PCT/US99/17179

My ref: P-0112PCT

**URGENT!** F237, 238/01se

## EXHIBITE

INTERNATIONAL BUREAU OF WIPO  
34. chemin des Colombettes  
1211 Geneva 20  
SWITZERLAND

Budapest, 26. January 2001

**Re:** Registration of Change in Person of Inventors  
**PCT Application:** PCT/US99/17179 29.07.1999  
**Priority:** 30.07.1998 US 60/094687

1. Reverting to my letter earlier this day I hereby ask to register the following further change according to PCT Rule 92/bis at your earliest convenience. The 30 months (Chapter II) period expires on 30. January 2001.
2. Because important subject matter of the claimed invention was based on the invention of authors whose names did not appear in the list of inventors as originally filed, the Applicant completed the list of inventors by adding of the following persons:
  - i) DR. HEGEDÚS, Lajos; chemical engineer; Hungarian citizen; Eötvös út 47 H-1121, Budapest, Hungary
  - ii) DR. KREMPELS, Krisztina; physician; Hungarian citizen; Ady E. út 204 H-1188 Budapest, Hungary
  - iii) DR. PAÁL, Krisztina; chemist, Hungarian citizen; Felsőzöldmáli út 80 H-1025 Budapest, Hungary
  - iv) DR. PETHŐ, Gábor; pharmacist; Hungarian citizen; Kassai út 10 H-1225, Budapest, Hungary

Thank you for your co-operation and help.

Respectfully



Dr. Eva Somfai  
patent attorney

U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

<b>PETITION UNDER 37 C.F.R. §§1.47(b) and 1.42</b>		Docket Number: 1662/460041 (formerly 11701/46007)	
Application Number 10/657,737	Filing Date September 3, 2003	Examiner Not Yet Assigned	Art Unit 1614
Invention Title <b>PHARMACEUTICALLY ACCEPTABLE COMPOSITION COMPRISING AN AQUEOUS SOLUTION OF PACLITAXEL AND ALBUMIN</b>		Inventor(s) <b>KADIMA et al.</b>	
Address to: Mail Stop Missing Parts Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450		I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Missing Parts, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on Date: <u>5/19/04</u> Reg. No. <u>46,877</u> Signature: <u>Tenshuk Kadima</u>	

SIR:

In response to the Notice to File Missing Parts of Application mailed November 26, 2003 Attorney for Applicants, Tenshuk A. KADIMA, Howard A. KAPLAN and Robert C. TUTTLE, hereby petitions the Commissioner under 37 C.F.R. §§1.47(b) and 1.42 hereby makes application for patent on behalf of and as agent for all the inventors. This petition includes proof of the pertinent facts showing that such action is necessary to preserve the rights of and to prevent irreparable damage to the parties.

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the United States. See attached copy of first page of published PCT application (Exhibit A).

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Tenshuk A. Kadima  
7 Woodington Bay  
Winnipeg, Manitoba, Canada R3P 1M6

Howard A. Kaplan  
18 Hillhouse Road  
Winnipeg, Manitoba, Canada R2V 2V9

Robert C. Tuttle  
782 Allegheny Drive  
Winnipeg, Manitoba, Canada R3T 5L2

The letters included copies of the application as filed and a Declaration form for signing and returning to Kenyon & Kenyon. Copies of the letters are attached (Exhibit F).

The letter addressed to Mr. Kadima was returned as unclaimed (Exhibit G).

The letter addressed to Mr. Tuttle was returned as "address incomplete" by the Canadian Postal Service (Exhibit H). The address used was the only address listed in the International Publication Number WO 00/06152 of PCT/US99/17179. We attempted to obtain address for the inventors through Lexis and Westlaw, but without success (Exhibit I).

We learned that one of the inventors, Dr. Howard Kaplan, was deceased. We contacted the attorney for the heir of Dr. Kaplan, Mr. Randall Gray of Pitblado Buchwald Asper, Manitoba, Canada. Mr. Gray referred us to Mr. Robert A. Watchman of that firm to resolve the matter. Mr. Gray, after discussing the matter with Mr. Kaplan's heir, Ms. Carole Grad, advised us by letter dated March 22, 2004 (Exhibit J) that Ms. Grad cannot sign the Declaration as worded, because she cannot declare that she has reviewed and understands the content of the specification, including the claims, among other things. (As the sister of the inventor, she does not have the scientific background to understand the invention.)

Accordingly, despite our diligent efforts to contact the originally-named inventors to obtain a signed Declaration, we were unable to obtain signatures from the three inventors. We therefore respectfully petition the Commissioner under 37 C.F.R. §§1.47(b) and 1.42 to make application for patent on behalf of and as agent for all the inventors and Human RT, assignee of PCT/US99/17179.

In view of the foregoing, Applicants respectfully request that this Petition be granted under these specific facts.

Applicants also respectfully request that the following four (4) additional inventors be added to this application:

After resolution of the 37 C.F.R. §§1.47(b) and 1.42 issues, Applicants will submit formal documents to add the above-mentioned additional four inventors to this application. These inventors (Lajos HEGEDUS, Krisztina KREMPELS, Krisztina PAAL and Gabor PETHO) have been previously included in the PCT (see Exhibit E).

A copy of the Notice to File Missing Parts of Application is also enclosed.

Applicants respectfully request a four-month extension of time to respond to the Notice to File Missing Parts of Nonprovisional Application, Filing Date Granted, for which a response period expiring on January 26, 2004 was set. The extended period expires on May 26, 2004.

The Commissioner is hereby authorized to charge payment of the following fees to the deposit account of **Kenyon & Kenyon, No. 11-0600**:

- 1) Basic Filing Fee of \$770.00;
- 2) Additional claims fee of \$1,106.00;
- 3) 37 C.F.R. §1.17(i) petition fee of \$130.00;
- 4) 37 C.F.R. § 1.136(a) extension fee of **\$1,480.00**; and
- 5) 37 C.F.R. § 1.116(e) surcharge of \$130.00.

The Commissioner is also authorized to charge any additional fees and credit any overpayment in connection with this communication to the deposit account of Kenyon & Kenyon, No. 11-0600. A copy of this communication is enclosed herewith for charging purposes.

Respectfully submitted,

Dated: 5/19/04

By Siu K. Lo  
Siu K. Lo  
Reg. No. 46,877

KENYON & KENYON  
One Broadway  
New York, New York 10004  
Tel: (212) 425-7200  
Fax: (212) 425-5288

CUSTOMER NUMBER 26646

2month  
0007350  
TLS

Filing



Patrick J. Birde  
Direct 212.908.6452  
pbirde@kenyon.com

One Broadway  
New York, NY 10004-1050  
212.425.7200  
Fax 212.425.5288

## EXHIBIT F

July 9, 2003

**VIA REGISTERED MAIL -**  
**Return Receipt Requested**

Mr. Tenshuk A. Kadima  
7 Woodington Bay  
Winnipeg, Manitoba  
Canada R3P 1M6

Re: U. S. Patent Application Serial No. 10/293,426  
PHARMACEUTICALLY ACCEPTABLE COMPOSITION  
COMPRISING AN AQUEOUS SOLUTION OF  
PACLITAXEL AND ALBUMIN  
Our Ref: 111701/46003

Dear Mr. Kadima:

We are contacting you on behalf of our client, Human RT.

As you may recall, Human RT purchased the rights to the above-referenced invention from Novopharm Biotech Inc. A patent application has been filed in the United States and has been assigned Serial No. 10/293,426. In order to complete the filing requirements for the application, we are now required to file a Declaration signed by all the inventors. A Declaration form is enclosed along with a copy of the application as filed in the United States Patent Office for your review.

Please sign and date the Declaration form where indicated and return the signed form to us as soon as possible. A postage paid DHL return envelope is enclosed for your convenience in returning the form.

If we do not hear from you within two (2) weeks from the date of this letter, we will assume you are unwilling to sign the form and will proceed accordingly.

Please feel free to contact myself (212-908-6452) or Mary Werner (212-908-6183) or in writing if you have any questions in this matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Patrick J. Birde".

Patrick J. Birde

Enclosures

cc: Dr. Eva Somfai (w/o enc.)  
Steven J. Lee, Esq. (w/o enc.)



Patrick J. Birde  
Direct 212.908.6452  
[pbirde@kenyon.com](mailto:pbirde@kenyon.com)

One Broadway  
New York, NY 10004-1050  
212.425.7200  
Fax 212.425.5288

July 9, 2003

**VIA REGISTERED MAIL -**  
***Return Receipt Requested***

Mr. Robert C. Tuttle  
782 Allegheny Drive  
Winnipeg, Manitoba  
CANADA R3T 5L2

Re: U. S. Patent Application Serial No. 10/293,426  
PHARMACEUTICALLY ACCEPTABLE COMPOSITION  
COMPRISING AN AQUEOUS SOLUTION OF  
PACLITAXEL AND ALBUMIN  
Our Ref: 11701/ 46003

Dear Mr. Tuttle:

We are contacting you on behalf of our client, Human RT.

As you may recall, Human RT purchased the rights to the above-referenced invention from Novopharm Biotech Inc. A patent application has been filed in the United States and has been assigned Serial No. 10/293,426. In order to complete the filing requirements for the application, we are now required to file a Declaration signed by all the inventors. A Declaration form is enclosed along with a copy of the application as filed in the United States Patent Office for your review.

Please sign and date the Declaration form where indicated and return the signed form to us as soon as possible. A postage paid DHL return envelope is enclosed for your convenience in returning the form.

If we do not hear from you within two (2) weeks from the date of this letter, we will assume you are unwilling to sign the form and will proceed accordingly.

Please feel free to contact myself (212-908-6452) or Mary Werner (212-908-6183) or in writing if you have any questions in this matter.

Sincerely,

A handwritten signature in black ink, appearing to read 'John Birde'. Below the signature, the name 'Patrick J. Birde' is printed in a smaller, standard font.

Enclosures

cc: Dr. Eva Somfai (w/o enc.)  
Steven J. Lee, Esq. (w/o enc.)

New York Washington, DC Silicon Valley [www.kenyon.com](http://www.kenyon.com) 608453



Patrick J. Birde  
Direct 212.908.6452  
pbirde@kenyon.com

One Broadway  
New York, NY 10004-1050  
212.425.7200  
Fax 212.425.5288

July 9, 2003

**VIA REGISTERED MAIL -**  
**Return Receipt Requested**

Mr. Howard A. Kaplan  
18 Hillhouse Road  
Winnipeg, Manitoba  
CANADA R2V 2V9

Re: U. S. Patent Application Serial No. 10/293,426  
PHARMACEUTICALLY ACCEPTABLE COMPOSITION  
COMPRISING AN AQUEOUS SOLUTION OF  
PACLITAXEL AND ALBUMIN  
Our Ref: 11701/ 46003

Dear Mr. Kaplan:

We are contacting you on behalf of our client, Human RT.

As you may recall, Human RT purchased the rights to the above-referenced invention from Novopharm Biotech Inc. A patent application has been filed in the United States and has been assigned Serial No. 10/293,426. In order to complete the filing requirements for the application, we are now required to file a Declaration signed by all the inventors. A Declaration form is enclosed along with a copy of the application as filed in the United States Patent Office for your review.

Please sign and date the Declaration form where indicated and return the signed form to us as soon as possible. A postage paid DHL return envelope is enclosed for your convenience in returning the form.

If we do not hear from you within two (2) weeks from the date of this letter, we will assume you are unwilling to sign the form and will proceed accordingly.

Please feel free to contact myself (212-908-6452) or Mary Werner (212-908-6183) or in writing if you have any questions in this matter.

Sincerely,  
  
Patrick J. Birde

Enclosures

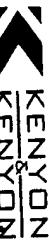
cc: Dr. Eva Somfai (w/o enc.)  
Steven J. Lee, Esq. (w/o enc.)

New York Washington, DC Silicon Valley [www.kenyon.com](http://www.kenyon.com) 608451

ORK, N. Y. 10004

EXHIBIT

G



KENYON  
&  
KENYON

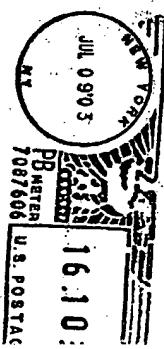
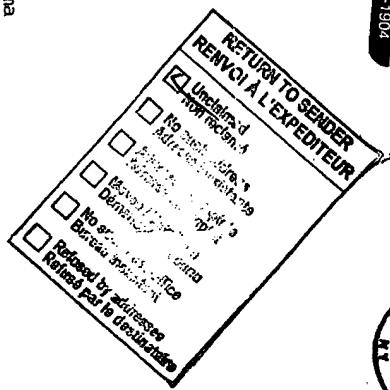
Intellectual Property Law

3 Broadway  
New York, NY 10004-1050

TURN TO SENDER  
VOIR L'EXPÉDITEUR

Mr. W. D. Suddington Bay  
Winnipeg, Manitoba, CANADA R3P 1M6

- Undelivered
- Non-existent
- No such address
- Address too distant
- Address incomplete
- Incorrect name and address
- Post Office
- Bureau missing
- No such address
- Refused by addressee
- Refused per te destination



**Return Receipt for International Mail**  
Registered, Insured, Recorded Delivery, Express Mail

Postmark: JULY 10 1989

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**From:** Werner, Mary  
**Sent:** Friday, August 01, 2003 2:03 PM  
**To:** Butler, Timothy  
**Subject:** RE: 11701/46001 - for Tuesday

Thanks, Tim.

---Original Message---

**From:** Butler, Timothy  
**Sent:** Friday, August 01, 2003 2:01 PM  
**To:** Werner, Mary  
**Subject:** RE: 11701/46001 - for Tuesday

Mary

It turns out that they can only obtain this information for people in the US. I'm going to hold on to this and try Westlaw next week. This was the answer which I received from your Lexis representative.

---Original Message---

**From:** Werner, Mary  
**Sent:** Thursday, July 24, 2003 6:36 PM  
**To:** Butler, Timothy  
**Subject:** 11701/46001 - for Tuesday

Tim,

These are the inventors in Canada for whom we need updated addresses:

KADIMA, Tenshuk, A., 7 Woodington Bay, Winnipeg, Manitoba R3P 1M6, CA 02

KAPLAN, Howard, A., 18 Hillhouse Road, Winnipeg, Manitoba R2V 2V9, CA 03

TUTTLE, Robert, C., 782 Allegheny Drive, Winnipeg, Manitoba R3T 5L2 / CA 04

Thanks.

Mary

Werner, Mary

---

**From:** Butler, Timothy  
**Sent:** Wednesday, August 06, 2003 7:22 PM  
**To:** Werner, Mary  
**Subject:** RE: 11701/46001 - for Tuesday

Mary  
I tryed again with West law . sorry no results

-----Original Message-----

**From:** Werner, Mary  
**Sent:** Thursday, July 24, 2003 6:36 PM  
**To:** Butler, Timothy  
**Subject:** 11701/46001 - for Tuesday

Tim,

These are the inventors in Canada for whom we need updated addresses:

KADIMA, Tenshuk, A., 7 Woodington Bay, Winnipeg, Manitoba R3P 1M6, CA 02  
KAPLAN, Howard, A., 18 Hillhouse Road, Winnipeg, Manitoba R2V 2V9, CA 03  
TUTTLE, Robert, C., 782 Allegheny Drive, Winnipeg, Manitoba R3T 5L2 / CA 04

Thanks.

Mary

EXHIBIT J

2500 - 360 Main Street  
Winnipeg, Manitoba  
Canada R3C 4H6

Tel. (204) 956 0560  
Fax (204) 957 0227  
E-mail firm@pitblado.com

VIA TELECOPIER 212-425-5288

March 22, 2004

Kenyon & Kenyon  
One Broadway  
New York, NY 10004-1050

**Attention: Siu K. Lo**

Dear Sir:

**Re: U.S. Patent Application Serial No. 10/293,426  
Your Reference: 1662/46003**

This will acknowledge receipt of your letter dated March 11, 2004 enclosing documentation with respect to the above-noted application.

As you may recall in our telephone conversation of September 3, 2003, because of the particular wording of the inventor's declaration for the United States, the representative of Dr. Kaplan's estate cannot sign the declaration. That is, the wording requires her to declare, under threat of penalty, that she has reviewed and understands the content of the specification, including the claims, amongst other things.

We wish to emphasize that Ms. Grad does not wish to appear to be uncooperative and she is not disputing the application or your client's entitlement to the invention, it is simply that she cannot sign the declaration as worded.

In our telephone discussion, I referred to other patent applications in which the same issue arose in which the applicant proceeded on the basis that the representative "refuses" to sign the declaration, which I believe is provided for in 37 CFR 1.42.

In our September 3, 2003 telephone conversation, you indicated that you believe the rules might have provided for some variation when the documents were to be signed by a representative. However, unless there is some other wording for the declaration, the representative of Dr. Kaplan's estate will not be able to sign.

Yours very truly,

PITBLADO

per: *Doreen Wager*  
Robert A. Watchman  
RAW:dew

for

ORK, N. Y. 10004

EXHIBIT

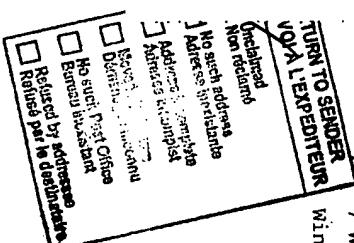
6

To: Patrick J. Birde

7th floor

1 Aug 18 2 24 PM '03

RECEIVED  
KENYON & ELLIOTT  
CHEMISTS  
NEW YORK

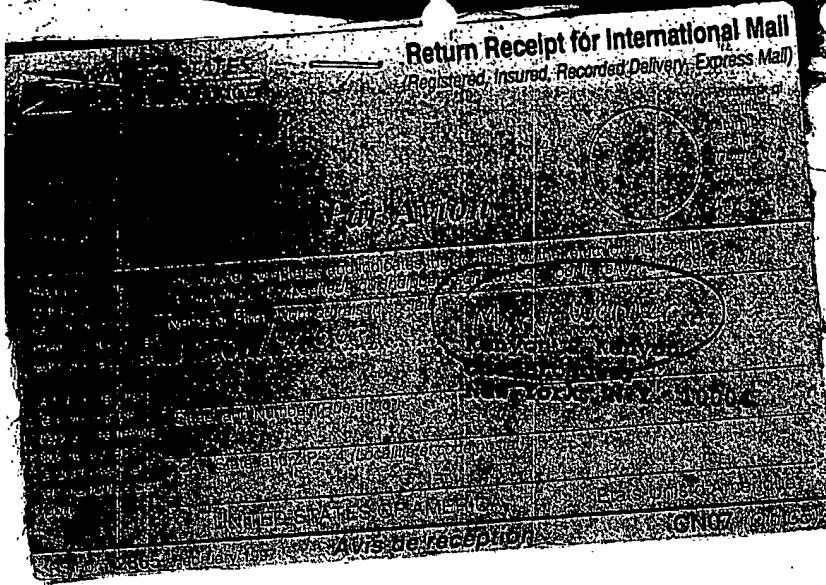


The logo for Kenyon & Kenyon is displayed. It features a large, bold, black 'K' mark on the left. To the right of the 'K' is the word 'KENYON' in a bold, black, sans-serif font, with a smaller '&' symbol positioned between 'YON' and 'KEN'. Below 'KENYON' is another 'K' mark, which is slightly smaller and oriented vertically.

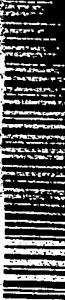
Broadway  
Park, NY 10004-1050

Mr. Denshuk A. Kadima  
7 Washington Bay  
Winnipeg, Manitoba, CANADA R3P 1M6





K 605 899-905 US  
(102595) 39-M-1904



One Broadway  
New York, NY 10004-1050

Mr. Robert C. Tuttle  
782 Allegheny Drive  
Winnipeg, Manitoba, CANADA R3T 5L2

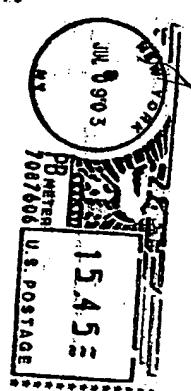
Address incomplete  
adres incomplète

ADDRESS INCOMPLETE // ADRESSE INCOMPLÈTE

RETURN TO SENDER // RETOUR AU ENVOI A L'EXPÉDITEUR

NY 10004 USA

Burke



**SOMFAI & PARTNERS**

Industrial Rights Co.Ltd.

H-1137 Budapest

Pozsonyi út 38.

Hungary

O Special Delivery

X Air mail X Registered

O Express

O Also by fax: - page(s)

Nº: 00 1 212 425 5288

Your letter: 22.06.2004

Copy:

Mr. Silver 1468/01

Mr. Friedman 1469/01

Tel:(361)3495-298

Fax:(361)3502-623

Law Office Kenyon & Kenyon  
One Broadway  
NEW YORK N.Y. 10004-1050  
U.S.A.  
X

Budapest, 08. September 2004

1467/04kj

Mr.

Attention of Patrick J. Birde!

Dear Colleagues,

Re: Continuation Patent Application Nº 10/657737 of  
HUMAN RT "Taxalb2" based on US 60/094687  
PCT/US99/17179 (originally by Novopharm)  
My ref: P-0112 US Please quote!  
Your ref: 1662/460041

1) Please find enclosed the original signed

• Declaration.

5 pages \*

2) The signature of Dr. Gábor Pethő is missing. Since we are  
not able to receive a new one, I suggest to consider my  
suggestions of my letters dated 19.17.2001 and 28.06.2004.

Sincerely yours

  
Dr. Eva Somfai

Enclosure: \* as above 5 pages

P-0112US

1/1

U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

**DECLARATION**

ATTORNEY'S DOCKET NO.  
11701/46003

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled **PHARMACEUTICALLY ACCEPTABLE COMPOSITION COMPRISING AN AQUEOUS SOLUTION OF PACLITAXEL AND ALBUMIN**, Serial No. 10/293,426, which is a continuation of U.S. Serial 09/947,420 filed September 5, 1991, which is a continuation of 09/744,827, which is the U.S. national phase of International Application PCT/US99/17179, filed July 29, 1999.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

**PRIOR UNITED STATES APPLICATION(S)**

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below.

APPLICATION NUMBER	FILING DATE (day, month, year)
60/094,687	30 July 1998

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s), or §365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this

application:

APPLICATION NUMBER	FILING DATE (day, month, year)	STATUS (i.e. Patented, Pending, Abandoned)
09/744,827	30 January 2001	Abandoned
09/947,420	05 September 2001	Abandoned

SEND CORRESPONDENCE, AND DIRECT TELEPHONE CALLS TO:

Steven J. Lee, Esq.  
KENYON & KENYON  
One Broadway  
New York, New York 10004-1050

CUSTOMER NUMBER 26646

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	KADIMA	Tenshuk	A.
RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	Winnipeg	Manitoba	Canada
POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY
	7 Woodington Bay	Winnipeg	Canada R3P 1M6
Signature		Date	

FULL NAME OF INVENTOR	FAMILY NAME (Deceased) <b>KAPLAN</b>	FIRST GIVEN NAME Howard	SECOND GIVEN NAME A.
RESIDENCE & CITIZENSHIP	CITY Winnipeg	STATE OR FOREIGN COUNTRY Manitoba	COUNTRY OF CITIZENSHIP Canada
POST OFFICE ADDRESS	POST OFFICE ADDRESS 18 Hillhouse Road	CITY Winnipeg	STATE & ZIP CODE/COUNTRY Canada R2V 2V9
Signature (Deceased - See Below)		Date	
<p>Heir and Legal Representative of Howard KAPLAN(Deceased)</p> <p>Residence:</p> <p>Citizenship: _____</p> <p>Signature: _____</p> <p>Date: _____</p>			
FULL NAME OF INVENTOR	FAMILY NAME <b>TUTTLE</b>	FIRST GIVEN NAME Robert	SECOND GIVEN NAME C.
RESIDENCE & CITIZENSHIP	CITY Winnipeg	STATE OR FOREIGN COUNTRY Manitoba	COUNTRY OF CITIZENSHIP Canada
POST OFFICE ADDRESS	POST OFFICE ADDRESS 782 Allegheny Drive	CITY Winnipeg	STATE & ZIP CODE/COUNTRY Canada R3T 5L2
Signature		Date	

FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	HEGEDUS	Lajos	
RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	Budapest	Hungary	Hungary
POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY
	H-1121 Eotvos ut 47	Budapest	Hungary
Signature	X Lajos		Date 08/12/2004
FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	KREMPELS	Krisztina	
RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	Budapest	Hungary	Hungary
POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY
	H-1188 Ady E. ut 204	Budapest	Hungary
Signature	X 07/15/2004		
FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	PAAL	Krisztina	
RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	Budapest	Hungary	Hungary
POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY
	H-1025 Felsozoldmali ut 80	Budapest	Hungary
Signature	X Paul Lechner	Date 2004 Aug. 6.	

FULL NAME OF INVENTOR	FAMILY NAME  PETHO	FIRST GIVEN NAME  Gabor	SECOND GIVEN NAME
RESIDENCE & CITIZENSHIP	CITY  Budapest	STATE OR FOREIGN COUNTRY  Hungary	COUNTRY OF CITIZENSHIP  Hungary
POST OFFICE ADDRESS	POST OFFICE ADDRESS  H-1225 Kassai ut 10	CITY  Budapest	STATE & ZIP CODE/COUNTRY  Hungary
Signature 		Date	

5 of 5

**SOMFAI & PARTNERS**

Industrial Rights Co. Ltd.

H-1137 Budapest

Hungary

Special Delivery

Air mail  Registered

Express

Also by fax: 2 page(s) + 10

Nº: 00 1 212 425 5288

Your letter: 23/06/2004

Copy for information:

Dr. Livneh 1189/04

Dr. Haber 1186/04

Mr. Silver 1187/04

Dr. Benedek 1190/04

Mr. Friedman 1191/04

Dr. Hegedűs 1192/04

Tel:(361)3495-298

Fax:(361)3502-623

Law Office Kenyon & Kenyon  
One Broadway  
NEW YORK N.Y. 10004-1050  
U.S.A.  
X

Budapest, 28. June 2004

F1184, 1185/04a6

Attention of Mr. Patrick J. Birde!

**PRIVILEGED AND CONFIDENTIAL!**

Dear Mr. Birde, dear Colleagues,

Re: Continuation Patent Application in US Nº 10/657737 of  
HUMAN RT "TAXALB-2" based on US 60/094687  
PCT/US99/17179 (originally by Novopharm)

Your ref: 1662/460041 Mrs. M.C. Werner

My ref. P-0112US-B

Completion of List of Inventors in Cont Appl.

Dear Patrick, I was more than pleased to make your acquaintance at the AIPPI conference in Geneva and I thank you again for inviting me to your company's 125 years celebration reception in the exquisite palace of the ancient "shooters".

**I. INVENTORS**

1. Thank you for your above fax letter (which arrived here 23/06/2004). You informed me that you had filed a continuation application and you now enclose forms which you ask me to return by fax complete with the Hungarian inventors' signature. You wish to file these in order that you try to accomplish the list of inventors now only comprising inventors Kadima, Kaplan and Tuttle. You request me to send you the signed version before the due date which is the 28<sup>th</sup> of June (to-day).
2. Please ask for an extension of time to collect the signatures. I have to add that none of the inventors can be found at Human Rt. anymore. In addition: one of the

inventors lives in Canada. Thus to collect all names on one single document is a lengthy program indeed.

3. Please advise by return whether it would be at least adequate to have the inventors sign the document separately (each inventor on a different document). This might speed up the procedure somewhat for those who are ready to sign it.
4. However it is highly dubious whether inventor Pethő will sign the declaration at all. He already refused a similar declaration for other countries stating that he now works for a company who would not allow him to sign anything of the kind.
5. Thus in Canada, Europe and Hungary we used already available documents signed by the inventor's team in relation to the "taxalbin-1" application filed by Human based on the invention of the 4 Hungarian inventors (whose names have to be added in the present matter):
  - a) in Canada we filed an
    - Affidavit with enclosed
    - assignments related to  
the Canadian "taxalbin-1"  
application dated June 19997 pages \*
  - b) in Europe we filed a
    - declaration  
on the basis of the enclosed transfer of  
rights dated 01/08/1997 and signed before  
filing of the "Taxalbin-1" Hungarian  
priority document.4 pages \*

The "taxalbin-1" series corresponds to your file 1662/53301 - our files P-9830US-A, B and C". It might be perhaps possible to rely on the signed documents filed in the USA(?) In Europe completion of inventor's names was already officially accepted.

## II. CONTINUATION APPLICATIONS

6. You indicated that you had already filed a continuation application. Please let me have the details of said application (filing date and forms). Please also let me have the data of the next new application which you decided to file on 28. June 2004. May I ask the reason why such series of applications is necessary?

Sincerely yours  
Dr. Eva Somfai

Enclosure:  
11 pages

*Best regards*

*Eva Somfai*

Re: Canadian Patent Application No. 2,362,338  
Applicant: Human Serum & Pharmaceutical  
Manufacturing  
Title: Pharmaceutically Acceptable  
Composition Comprising an Aqueous  
Solution of Paclitaxel and Albumin  
Filed: July 29, 1999

ENCLOSURE I

**AFFIDAVIT OF DR. EVA SOMFAI**

IN THE MATTER OF Canadian Patent Application No. 2,362,338, (the "Present Application") I, Dr. Eva Somfai, in the City of Budapest, Hungary, MAKE OATH AND SAY:

1. I am a Patent Agent with the firm of Somfai & Partners who act on behalf of Human RT, the applicant of the Present Application. As such, I have personal knowledge of the facts stated in this my affidavit.
2. An assignment document, a copy of which is attached as Exhibit "A" to this my affidavit, was recorded in the Canadian Patent Office on August 26, 1999 under Document Registration No. 5048332 for Canadian Patent Application No. 2,269,923 which is based on International Application No. PCT/HU98/00086.
3. The assignment document provided in Exhibit "A" to this my affidavit transfers all right, title and interest of the invention disclosed in Canadian Patent Application No. 2,269,923 from the inventors listed as Krisztina Krempels, Krisztina Paál, Gábor Pethö and Lajos Hegedüs to Human RT, the applicant of both Canadian Patent Application No. 2,269,923 and the Present Application.
4. All of the subject matter disclosed in the specification of the Present Application is also disclosed in Canadian Patent Application 2,269,923.

5. It is respectfully submitted that the assignment document provided in Exhibit "A" to this my affidavit from the inventors of the Present Application listed as Krisztina Krempels, Krisztina Paál, Gábor Pethö and Lajos Hegedüs transferring all rights in and to the invention disclosed in Canadian Patent Application No. 2,269,923 to the applicant Human RT of the Present Application should also be recorded against the Present Application.

**SWORN BEFORE ME** at the City of  
Hungary this      day of  
2003

)  
)  
)  
)



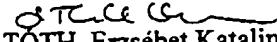
DR. EVA SOMFAI

A Notary Public and Commissioner

  
**Dr. TÓTH ERZSÉBET KATALIN**  
Notary

1136 Budapest, Tátra u. 15/a.  
Tel/fax: 349-3404, 329-3034

File No: 4256/2003. -----  
English language licence No: 35167/1991. IM III. -----  
Before me, the undersigned Notary in and for the City of Budapest, personally appeared  
Ms. Dr. SOMFAI, Éva, domiciled at Budapest, I. Táncsics M. u. 8. I. I., Republic of  
Hungary, who proved identity by the Hungarian Identity Card No. AH 305918, she  
signed this document in my presence. -----  
At Budapest on this 2<sup>nd</sup> (second) day of December, 2003 (two thousand and three). -----

  
Dr. TÓTH, Erzsébet Katalin  
Notary



This is Exhibit "A" referred to in  
the Affidavit of

DR. EVA SOMFAI

*Eva Somfa*  
*SQ*

Sworn before me this                    day of  
   , 2003

A Commissioner, etc.



Dr. TÓTH ERZSÉBET KATALIN

Notary

1136 Budapest, Tátra u. 15/a.  
Tel/fax: 349-3404, 329-3034

File No: 4256/2003.

English language licence No: 35167/1991. IM III.

Before me, the undersigned Notary in and for the City of Budapest, personally appeared Ms. Dr. SOMFAI, Éva, domiciled at Budapest, I. Táncsics M. u. 8. I. 1., Republic of Hungary, who proved identity by the Hungarian Identity Card No. AH 305918, she signed this document in my presence.

At Budapest on this 2<sup>nd</sup> (second) day of December, 2003 (two thousand and three).



Dr. TÓTH, Erzsébet Katalin  
Notary

CANADA

P-0112-CF

Joint Inventors

Assignment

In consideration of One (\$1.00) Dollar, and other good and valuable consideration paid to us by HUMAN Rt. whose full post office address is Támcics út 82, H-2100 Gödöllő, Hungary, hereinafter called the Assignee, the receipt whereof is hereby acknowledged, we do hereby sell and assign unto the said Assignee, all our right, title and interest in Canada in and to our invention relating to:

**PHARMACEUTICAL COMPOSITIONS CONTAINING PLASMA PROTEIN**

as fully described and claimed in the Canadian patent application for such invention based on International Application No. PCT/HU98/00086, and to all our corresponding right, title and interest in and to any patent which may issue therefor.

SIGNED at (1)  
this <sup>29</sup> day of <sup>June</sup>, 1999.

Inventor:

Gábor Dr.  
Lajos HEGEDÜS

Witness:

Hajdi László



...2

Gödöllő

P-0112CA

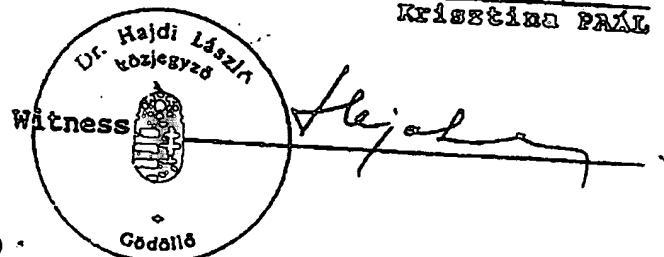
SIGNED at (1) X  
this X 29 day of X JUNE , 1999.

Inventor: Krisztina Krempeles  
Krisztina KREMPELES X



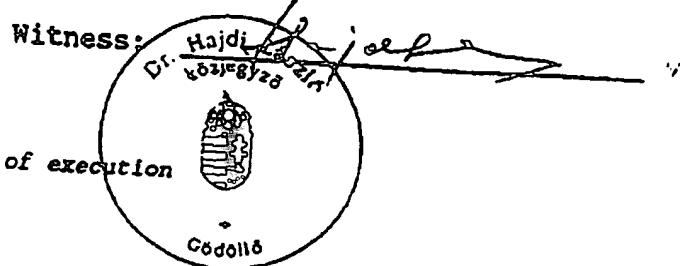
SIGNED at (1) X  
this X 29 day of X June , 1999.

Inventor: Fazl K. Kálai  
Krisztina PÁL



SIGNED at (1) X  
this X 29 day of X June , 1999.

Inventor: Ervin Petró  
Ervin PETRÓ



(1) Insert place and date of execution

G. RONALD BELL & ASSOCIATES

P-0112.CA



Dr. HAJDI LÁSZLÓ  
1. sz. KÖZJEGYZŐ  
2100 Gödöllő, Remény krt. 6., Pf. 167.  
Tel./Fax: /28/ 430-063, 415-313. Rádiótel.: 06 30 489 426

## T A N Ú S Í T V Á N Y

HITELESÍTÉSEK KÖNYVE: 1405., 1406., 1407., 1408/1999. ügyszám:----  
Alulírott, dr. Hajdi László gödöllői közjegyző tanúsítom, hogy---  
Dr. HEGEDÜS LAJOS (Bp., XII., 1952. 03. 28., an.: Kardos Julian-  
na)), Budapest, XI., Oltvány árok u. 16. II/2. (szig.szám: AF851-  
367)-----  
Dr. KREMPPELS KRISZTINA (Bp., VIII., 1967. 07. 09., an.: Hancke Ma-  
rianna), Budapest, XVIII., Ady E. u. 204. (szig.szám: AF857343)---  
PAÁL KRISZTINA (Bp., XII., 1969. 05. 12., an.: Liptay Klára),---  
Budapest, II. Felsőzöldmáli u. 80. (szig.szám: AU-VI. 683056)---  
Dr. PETHŐ GÁBOR (Bp., VIII., 1954. 05. 16., an.: Varjas Ferdinand-  
da), Budapest, XII., Kassai u. 10. (szig.szám: AU-VI. 596319)---  
szám alatti lakos személyazonossága megfelelő módon való igazolá-  
sa után az idefűzött - általam nem beszélt, nem értett - angol---  
nyelvű dokumentumot a mai napon előttem saját kezűleg írta alá---  
Kelt Gödöllőn, 1999. Egyezekilencszázkilencvenkilencedik évi,---  
Június hó 29. Huszonkilencedik napján.-----

Dr. Hajdi László  
közjegyző



ÉRKEZETT

## BEETZ &amp; PARTNER

Patentanwälte  
 European Patent Attorneys  
 European Trade Mark Attorneys

BEETZ &amp; PARTNER Steinendorfstr. 10 D-80538 München

## ENCLOSURE 2

26-1991) 2001 MARCH 2  
-2000)

Dipl.-Ing. J. SIEGFRIED  
 Prof. Dr.rer.nat. W. SCHMITT-FUMIAN  
 Dipl.-Phys. Dr.rer.nat. C.-M. MAYR  
 Dipl.-Ing. A. PFEIFFER  
 Dipl.-Ing. B. MATIAS  
 Rechtsanwältin P. KOTSCH

European Patent Office

Ihr Zchn.  
Your Ref.

80298 München

Unser Zchn. 64-56.424EP/SF;fk  
Our Ref.

München March 16, 2001

European Patent Application 99937616.3 of July 29, 1999  
 Novopharm Biotech, Inc.

According to our telephone conversation of March 13, 2001, we herewith file the  
 Designation of Inventor for the additional inventors.

Patentanwälte  
 BEETZ & PARTNER  
 Association no. 71

W. SCHMITT-FUMIAN

Encls.

2001 MARCH 21

## ERFINDERNENNUNG / DESIGNATION OF INVENTOR / DESIGNATION DE L'INVENTEUR

(falls Anmelder nicht oder nicht allein der Erfinder ist; where the applicant is not the inventor or is not the sole inventor; si le demandeur n'est pas l'inventeur ou l'inventeur unique)

Nr. der Anmeldung oder, falls noch nicht bekannt, Bezeichnung der Erfindung  
 Application N° or, if not yet known, title of the invention  
 N° de la demande ou, si ce dernier n'est pas encore connu, titre de l'invention

Zeichen des Anmelders oder Vertreters  
 Applicant's or representative's reference  
 Référence du demandeur ou du mandataire  
 (max. 15 Positionen / max. 15 spaces /  
 15 caractères au maximum )

64-56.424EP/SF;fk

99937616.3

In Sachen der obenbezeichneten europäischen Patentanmeldung nennt (nennen) der (die) Unterzeichnete(n)<sup>1</sup>  
 In respect of the above European patent application I (we), the undersigned<sup>1</sup>  
 En ce qui concerne la demande de brevet européen susmentionnée le (s) soussigné(s)<sup>1</sup>

BEETZ & PARTNER  
 Patentanwälte  
 Steinsdorfstr. 10  
 D-80538 München

Zusammenschluß Nr. 71

als Erfinder<sup>2</sup>: **additional**  
 do hereby designate as inventor(s)<sup>2</sup>:  
 désigne(nt) en tant qu'inventeur(s)<sup>2</sup>:

- i) DR. HEGEDÜS, Lajos; chemical engineer;  
 Hungarian citizen;  
 Eötvös út 47  
 H-1121, Budapest, Hungary
- ii) DR. KREMPELS, Krisztina; physician; Hungarian citizen;  
 Ady E. út 204  
 H-1188 Budapest, Hungary
- iii) DR. PÁAL, Krisztina; chemist, Hungarian citizen;  
 Felszabadalmi út 80  
 H-1025 Budapest, Hungary
- iv) DR. PETHŐ, Gábor; pharmacist; Hungarian citizen;  
 Kassai út 10  
 H-1225, Budapest, Hungary

Der (Die) Anmelder hat (haben) das Recht auf das europäische Patent erlangt<sup>3</sup>  
 The applicant(s) has (have) acquired the right to the European patent<sup>3</sup>  
 Le(s) demandeur(s) a (ont) acquis le droit au brevet européen<sup>3</sup>



gemäß Vertrag vom  
 under an agreement dated  
 par contrat en date du

01.08.1997



als Arbeitgeber  
 as employer(s)  
 en qualité d'employeur(s)



durch Erbschaft  
 as successor(s) in title  
 par transfert successoral

Ort/Place/Lieu München

Datum/Date March 16, 2001

Unterschrift(en) des (der) Anmelder(s) oder Vertreter(s) /  
 Signature(s) of applicant(s) or representative(s) /  
 Signature(s) du (des) demandeur(s) ou du (des) mandataire(s)

W. SCHMITT-FUMIAN

BEETZ & PARTNER  
 Patentanwälte  
 Steinsdorfstrasse 10, D-80538 München

Name des (der) Unterzeichneten bitte mit Schreibmaschine wiederholen. Bei juristischen Personen bitte die Stellung des (der) Unterzeichneten innerhalb der Gesellschaft mit Schreibmaschine angeben! Please type name under signature in case of legal persons, the position of the signer within the company should also be typed! ou les noms des signataires doivent être également dactylographiés. Si il s'agit d'une personne morale, la position occupée au sein de celle-ci par le ou les signataires sera indiquée à la machine à écrire

Fußnoten befinden sich auf der Rückseite / Footnotes overleaf / Lo texto de los correos figura en verso

EPA/EPO/OEB Form 1002 11.98 (Int. Ed. 1/98)      bitte wenden! P.T.O. / T.S.V.P.

## NYILATKOZAT

## DECLARATION

Alulirott feltaláló(k)

The undersigned inventor(s)

Dr. Hegedüs Lajos

Dr. Hegedüs Lajos

Dr. Krámpels Krisztina

Dr. Krámpels Krisztina

Dr. Paál Krisztina

Dr. Paál Krisztina

Dr. Pethő Gábor

Dr. Pethő Gábor

kijelenti(k), hogy

declare(s), that

HUMAN Oltóanyagtermelő és  
Gyógyszergyártó Rt.HUMAN Serum Production and  
Medicine Manufacturing Co., Ltd

jogosult arra, hogy

is authorized to file in ..... a patent  
application for the subject matter of his/her  
patent application(s) entitled.

Method for parenteral delivery in therapeutic use of pharmacologically active compounds with  
poor solubility in water, and substantial binding to plasma proteins.

című .....

filed under No(s) .....

szám(ok) alatt ..... ban

in .....

benyújtott bejelentés(ei)nek tárgyát  
saját nevében szabadalomra

and to claim priority of said patent application.

bejelentse és a fent említett szabadalmi  
bejelentés(ek) elsőbbségi jogát igénybe vegye.

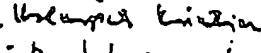
Name: Dr. Hegedüs Lajos

Date: 1997.08.01.

Signature(s). 

Name: Dr. Krámpels Krisztina

Date: 1997.08.01.

Signature(s). 

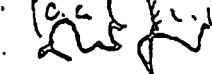
Name: Dr. Paál Krisztina

Date: 1997.08.01.

Signature(s). 

Name: Dr. Pethő Gábor

Date: 1997.08.01.

Signature(s). 

Name:

Date:

Signature(s)

Name:

Date:

Signature(s)

Name:

Date:

Signature(s)

U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

**DECLARATION**

ATTORNEY'S DOCKET NO.  
11701/46003

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled **PHARMACEUTICALLY ACCEPTABLE COMPOSITION COMPRISING AN AQUEOUS SOLUTION OF PACLITAXEL AND ALBUMIN**, Serial No. 10/293,426, which is a continuation of U.S. Serial 09/947,420, filed September 5, 1991, which is a continuation of 09/744,827, which is the U.S. national phase of International Application PCT/US99/17179, filed July 29, 1999.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

**PRIOR UNITED STATES APPLICATION(S)**

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below.

APPLICATION NUMBER	FILING DATE (day, month, year)
60/094,687	30 July 1998

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s), or §365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this

application:

APPLICATION NUMBER	FILING DATE (day, month, year)	STATUS (i.e. Patented, Pending, Abandoned)
09/744,827	30 January 2001	Abandoned
09/947,420	05 September 2001	Abandoned

SEND CORRESPONDENCE, AND DIRECT TELEPHONE CALLS TO:

Steven J. Lee



26646

PATENT TRADEMARK OFFICE

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	KADIMA	Tenshuk	A.
RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	Winnipeg	Manitoba	Canada
POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY
	7 Woodington Bay	Winnipeg	Canada R3P 1M6
Signature		Date	

FULL NAME OF INVENTOR	FAMILY NAME <b>KAPLAN</b>	FIRST GIVEN NAME Howard	SECOND GIVEN NAME A.
RESIDENCE & CITIZENSHIP	CITY Winnipeg	STATE OR FOREIGN COUNTRY Manitoba	COUNTRY OF CITIZENSHIP Canada
POST OFFICE ADDRESS	POST OFFICE ADDRESS 18 Hillhouse Road	CITY	STATE & ZIP CODE/COUNTRY
		Winnipeg	Canada R2V 2V9
Signature		Date	
FULL NAME OF INVENTOR	FAMILY NAME <b>TUTTLE</b>	FIRST GIVEN NAME Robert	SECOND GIVEN NAME C.
RESIDENCE & CITIZENSHIP	CITY Winnipeg	STATE OR FOREIGN COUNTRY Manitoba	COUNTRY OF CITIZENSHIP Canada
POST OFFICE ADDRESS	POST OFFICE ADDRESS 782 Allegheny Drive	CITY	STATE & ZIP CODE/COUNTRY
		Winnipeg	Canada R3T 5L2
Signature		Date	
FULL NAME OF INVENTOR	FAMILY NAME <b>HEGEDUS</b>	FIRST GIVEN NAME Lajos	SECOND GIVEN NAME
RESIDENCE & CITIZENSHIP	CITY Budapest	STATE OR FOREIGN COUNTRY Hungary	COUNTRY OF CITIZENSHIP Hungary
POST OFFICE ADDRESS	POST OFFICE ADDRESS H-1121 Eotvos ut 47	CITY	STATE & ZIP CODE/COUNTRY
		Budapest	Hungary
Signature		Date	

FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	KREMPELS	Krisztina	
RESIDENCE & CITIZENSHIP	CITY Budapest	STATE OR FOREIGN COUNTRY Hungary	COUNTRY OF CITIZENSHIP Hungary
POST OFFICE ADDRESS	POST OFFICE ADDRESS  H-1188 Ady E. ut 204	CITY	STATE & ZIP CODE/COUNTRY
		Budapest	Hungary
Signature	Date		
FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	PAAL	Krisztina	
RESIDENCE & CITIZENSHIP	CITY Budapest	STATE OR FOREIGN COUNTRY Hungary	COUNTRY OF CITIZENSHIP Hungary
POST OFFICE ADDRESS	POST OFFICE ADDRESS  H-1025 Felsozoldmali ut 80	CITY	STATE & ZIP CODE/COUNTRY
		Budapest	Hungary
Signature	Date		
FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	PETHO	Gabor	
RESIDENCE & CITIZENSHIP	CITY Budapest	STATE OR FOREIGN COUNTRY Hungary	COUNTRY OF CITIZENSHIP Hungary
POST OFFICE ADDRESS	POST OFFICE ADDRESS  H-1225 Kassai ut 10	CITY	STATE & ZIP CODE/COUNTRY
		Budapest	Hungary
Signature	Date		

U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

**DECLARATION**

ATTORNEY'S DOCKET NO.  
11701/46003

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled **PHARMACEUTICALLY ACCEPTABLE COMPOSITION COMPRISING AN AQUEOUS SOLUTION OF PACLITAXEL AND ALBUMIN**, Serial No. 10/293,426, which is a continuation of U.S. Serial 09/947,420, filed September 5, 1991, which is a continuation of 09/744,827, which is the U.S. national phase of International Application PCT/US99/17179, filed July 29, 1999.

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application:

APPLICATION NUMBER	FILING DATE (day, month, year)	STATUS (i.e. Patented, Pending, Abandoned)
09/744,827	30 January 2001	Abandoned
09/947,420	05 September 2001	Abandoned

SEND CORRESPONDENCE, AND DIRECT TELEPHONE CALLS TO:

Steven J. Lee



26646

PATENT TRADEMARK OFFICE

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	KADIMA	Tenshuk	A.
RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	Winnipeg	Manitoba	Canada
POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY
	7 Woodington Bay	Winnipeg	Canada R3P 1M6
Signature		Date	

FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	KAPLAN	Howard	A.
RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	Winnipeg	Manitoba	Canada
POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY
	18 Hillhouse Road	Winnipeg	Canada R2V 2V9
Signature		Date	
FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	TUTTLE	Robert	C.
RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	Winnipeg	Manitoba	Canada
POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY
	782 Allegheny Drive	Winnipeg	Canada R3T 5L2
Signature		Date	
FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	HEGBDUS	Lajos	
RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	Budapest	Hungary	Hungary
POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY
	H-1121 Eotvos ut 47	Budapest	Hungary
Signature		Date	

FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	KREMPELS	Krisztina	
RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	Budapest	Hungary	Hungary
POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY
	H-1188 Ady E. ut 204	Budapest	Hungary
Signature	Date		
FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	PAAL	Krisztina	
RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	Budapest	Hungary	Hungary
POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY
	H-1025 Felsozoldmali ut 80	Budapest	Hungary
Signature	Date		
FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	PETHO	Gabor	
RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	Budapest	Hungary	Hungary
POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY
	H-1225 Kassai ut 10	Budapest	Hungary
Signature	Date		

SOMFAI & PARTNER S  
H-1137 Budapest, Pozsonyi út 38  
Hungary

tel: (361)3495-298  
Fax:(361)3502-623

Special Delivery  
 Air mail  Registered  
 Express

Also by fax: 1 page(s) + 1

Nº: 00 41 22 740.14.35

Your letter:

Your ref: PCT/US99/17179

My ref: P-0112PCT

Please quote on all  
correspondence!

## EXHIBIT C

INTERNATIONAL BUREAU OF WIPO  
34, chemin des Colombettes  
1211 Geneva 20  
SWITZERLAND

### URGENT!

Budapest, 26. January 2001

P235,236/01se

Re:	Registration of Assignment of Application	
PCT Application:	PCT/US99/17179 29. 07. 1999	
PCT Publication:	WO 00/06152	10. 02. 2000
Priority:	30. 07. 1998	US 60/094687

1. The patent application in caption and all rights related thereto were assigned from the original PCT applicant Novopharm Biotech Inc., 30. Novopharm Court, Toronto, Ontario M1B 2K9, Canada.

2. Data of the present applicant and the signatory:

**Assignee:**  
HUMAN Rt.  
Táncsis út 82.  
H-2100 Gödöllő,  
Hungary

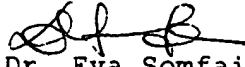
**Signatory:**  
Lajos HEGEDÜS  
managing director

3. Please register the above change according to PCT Rule 92/bis at your earliest convenience. The 30 months (Chapter II) period expires on 30. January 2001.

4. Please find enclosed the  
• Power of attorney signed by the new  
applicant  
appointing me to represent this application. 1 page \*

Thank you for your co-operation.

Respectfully

  
Dr. Eva Somfai  
patent attorney

Enclosure:

\*\* Fax and Mail: New Power of Attorney  
Fax and Mail: Assignment Deed (follows on receipt)

P-0112

1/1

**MEGHATA MAZÁS**

Alulirott

**HUMAN RT;**  
Gödöllő, Hungary

ezennel meghatalmazzuk(zom) a  
SOMFAI és TÁRSAI  
Iparjogi Kft-t

Szabadalmi ügyvivő:  
Dr jur. Somfai Éva  
vegyészmérnök

hogy az  
US 60/094687  
PCT/US99/17179  
-ra alapított,

Pharmaceutically Acceptable Composition  
Comprising an Aqueous Solution of  
Paclitaxel and Albumin

című szabadalom és/vagy bejelentés

Ügyben az illetékes hatóságok, bíróságok  
és hivatalok előtt teljes jogkörrel  
képviseljen.

Kelt/Date:

Név (Cég)/ Name (Firm):

**HUMAN RT.**

Cím/Address:

Táncsics M.u.82.  
H-2100 Gödöllő, Hungary

Aláírás(ok)/ Signature(s)::

**L. Hegedűs**  
Managing Director

Name and capacity of signatories

**POWER**

The undersigned

**HUMAN RT;**  
Gödöllő, Hungary

hereby appoint(s)  
**SOMFAI and PARTNERS**  
Industrial Rights Co. Ltd.

Patent Attorney:  
Dr jur. Eva Somfai  
eng. chem.  
concerning  
Patent and/or Application entitled

Pharmaceutically Acceptable Composition  
Comprising an Aqueous Solution of Paclitaxel  
and Albumin

Nº  
based on  
US 60/094687  
PCT/US99/17179

with full power of substitution and  
representation before the competent  
authorities, courts or offices.



(no legalization is required)

P-0112

11-11 A&O 11701-46001  
SOMFAI & PARTNERS

Industrial Rights Co.Ltd.  
H-1137 Budapest  
Hungary

EXHIBIT D  
RT  
Tel:(361)3495-298  
Fax:(361)3502-623

Special Delivery  
 Air mail  Registered  
 Express  
 Also by fax: 3+6 page(s)  
Nº: 001 212 425 5288  
Your letter: -

**URGENT!**  
**IMPORTANT!**

Law Office Kenyon & Kenyon  
One Broadway  
NEW YORK N.Y. 10004-1050  
U.S.A.  
X

Budapest, 26. January 2001

F231, 232/01kj

Attention of Mr. Steven J. Lee! and/or  
Mr. Patrick Bird!  
PRIVILEGED AND CONFIDENTIAL!

Dear Colleagues,

Re: New Patent Application in US of  
HUMAN RT "NOVBIO" based on US 60/094687  
PCT/US99/17179  
My ref: P-0112 US Please quote!  
Your ref: -  
NATIONAL APPLICATION TO BE FILED in US

Please

File a new patent application in Canada  
 Enter the national phase of the PCT application in caption.

To be filed: On/before **30. January 2001**

12 months priority  
 20 months PCT  
 **30 months PCT date.**

If it is possible to file within 31 months in your country please file timely before the due date.

Documents:	Now enclosed	Follows	Please inform	Remarks
Information sheet	X 2 pages			fax
PCT Publication cover	X 1 page			fax
Specification to be filed	see PCT publ			• 125 pages
Claims to be filed	see PCT publ			• 4 pages

Figures to be filed	see PCT publ			• 28 pages
Abstract	see PCT publ			• 1 page
Power		X		
Inventors decl.		X		
Transfer of rights		X		
Data of newly added inventors	X 1 page			• •
Priority document		X		
PCT Search Report				•
PCT Publication				•
Change of representation and owner filed at WIPO	X 1 page			
Completion of inventor's list filed at WIPO	X 2 pages			
Acceptance by WIPO			X	

- is already in your file (5934/2)
- • If you consider it would be better not to file this please
  - call me before filing any time between 9 and 19 our time
  - add the names when appropriate.

Please indicate by return fax what else you need. The outstanding documents will follow always with a copy of this letter.

We ask you to send the **filled-in Powers** and all other documents you need in the form **ready for signature**. Empty formulars will not be signed.

- The priority document was filed in English by the inventors Kadima Tenshuk, Kaplan Howard, Tuttle Robert C.
- The PCT application was filed by the assignor Novopharm Biotech, CA the prosecution was in English and the application was recently assigned. When writing this order letter the WIPO-registration of both the Assignment and completion of the list of inventors is still pending.

We await your debit notes in duplicate clearly indicating where and how you wish us to settle the same.

Please do not abandon this application if not expressly instructed to do so.

Please confirm receipt both of the faxed and the mail version  
of this order letter as well as the documents by fax.

Thanking you for your immediate attention and looking forward  
to have a good co-operation.

Sincerely yours



Dr. Eva Somfai  
chem. ing. patent attorney

Enclosure:

Fax:	6 page(s)
Air mail:	- page(s)
Spec. delivery	6 page(s)

SOMFAI & PARTNERS  
Industrial Rights Co.Ltd.  
H-1137 Budapest  
Hungary

Tel:(361)3495-298  
Fax:(361)3502-623

## INFORMATION SHEET FOR NEW PATENT APPLICATION

**TITLE:** Pharmaceutically Acceptable Composition  
Comprising an Aqueous Solution of  
Paclitaxel and Albumin

**APPLICANT:** HUMAN RT  
Táncsics M.u.82.  
H-2100 Gödöllő, Hungary

**PRIORITY:** 30.07.1998 US 60/094687

**PCT APPLICATION:** PCT/US99/17179 29.07.1999

**PCT PUBLICATION:** WO 00/06152 10.02.2000

**INVENTOR(S):** Kadima, Tenshuk  
Kaplan, Howard  
Tuttle, Robert C.  
Dr. Hegedűs, Lajos  
Dr. Krempels, Krisztina  
Dr. Paál, Krisztina  
Dr. Pethő, Gábor

I To BE  
ADDED  
WHEN  
APPROPRIATE

To be filed: On/before 30. January 2001

- 12 months priority
- 20 months PCT
- 30 months PCT date.

If it is possible to file within 31 months in your country please file timely before the due date.

### ASSIGNMENTS:

- The priority application was filed by:  
Inventors Kadima, Kaplan, Tuttle (CA)  
all of Novopharm Biotech, CA.
- The PCT application was filed by:  
Novopharm Biotech, CA, except in the US where it was filed by inventors Kadima, Kaplan, Tuttle.
- The application was assigned on HUMAN RT., HU registration of the change was requested in the international phase on 26.01.2001

- The national application has to be filed in the name of HUMAN RT., HU alone.  
The assignment documents will follow as soon as available.
- Because important subject matter of the claimed invention was based on the invention of the four Hungarian inventors now appearing in the list of inventors - registration of completion of the inventor's list was requested on 26.01.2001 at the WIPO.

SOMFAI & PARTNERS  
H-1137 Budapest, Pozsonyi út 8  
Hungary

Special Delivery  
 Air mail  Registered  
 Express

Also by fax: 1 page(s)

Nº: 00 41 22 740.14.35

Your letter:

Your ref: PCT/US99/17179

My ref: P-0112PCT

**URGENT!**

F237, 238/01sé

Te: (361)3495-298  
... (361)3502-623

## EXHIBITE

INTERNATIONAL BUREAU OF WIPO  
34, chemin des Colombettes  
1211 Geneva 20  
SWITZERLAND

Budapest, 26. January 2001

**Re:** Registration of Change in Person of Inventors  
**PCT Application:** PCT/US99/17179 29.07.1999  
**Priority:** 30.07.1998 US 60/094687

1. Reverting to my letter earlier this day I hereby ask to register the following further change according to PCT Rule 92/bis at your earliest convenience. The 30 months (Chapter II) period expires on 30. January 2001.
2. Because important subject matter of the claimed invention was based on the invention of authors whose names did not appear in the list of inventors as originally filed, the Applicant completed the list of inventors by adding of the following persons:
  - i) DR. HEGEDÜS, Lajos; chemical engineer; Hungarian citizen; Eötvös út 47 H-1121, Budapest, Hungary
  - ii) DR. KREMPELS, Krisztina; physician; Hungarian citizen; Ady E. út 204 H-1188 Budapest, Hungary
  - iii) DR. PAÁL, Krisztina; chemist, Hungarian citizen; Felsőzöldmáli út 80 H-1025 Budapest, Hungary
  - iv) DR. PETHŐ, Gábor; pharmacist; Hungarian citizen; Kassai út 10 H-1225, Budapest, Hungary

Thank you for your co-operation and help.

Respectfully

  
Dr. Eva Somfai  
patent attorney

U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

<b>PETITION UNDER 37 C.F.R. §§1.47(b) and 1.42</b>		Docket Number: <b>1662/460041</b> (formerly 11701/46007)	
Application Number <b>10/657,737</b>	Filing Date <b>September 3, 2003</b>	Examiner <b>Not Yet Assigned</b>	Art Unit <b>1614</b>
Invention Title <b>PHARMACEUTICALLY ACCEPTABLE COMPOSITION COMPRISING AN AQUEOUS SOLUTION OF PACLITAXEL AND ALBUMIN</b>		Inventor(s) <b>KADIMA et al.</b>	
<b>Address to:</b> Mail Stop Missing Parts Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450		I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Missing Parts, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on Date: <u>5/19/04</u> Reg. No. <u>46,877</u> Signature: <u>Tenshuk Kadima</u>	

SIR:

In response to the Notice to File Missing Parts of Application mailed November 26, 2003 Attorney for Applicants, Tenshuk A. KADIMA, Howard A. KAPLAN and Robert C. TUTTLE, hereby petitions the Commissioner under 37 C.F.R. §§1.47(b) and 1.42 hereby makes application for patent on behalf of and as agent for all the inventors. This petition includes proof of the pertinent facts showing that such action is necessary to preserve the rights of and to prevent irreparable damage to the parties.

The above-identified application is a continuation of U.S. Patent Application Serial No. 10/293,426, filed November 12, 2002, which is a continuation of Serial No. 09/947,420, filed September 5, 2001, which is a continuation of Serial No. 09/744,827 which is a 371 of PCT/US99/17179, filed July 29, 1999, which International Application claims the benefit of provisional application Serial No. 60/094,687, filed July 30, 1998.

The International Application was filed in the name of Novopharm Biotech, Inc. as Applicant for all designated States except the United States (Exhibit A). The inventors, Tenshuk KADIMA, Howard KAPLAN and Robert C. Tuttle, were listed as the applicants for

the United States. See attached copy of first page of published PCT application (Exhibit A).

Novopharm Biotech, Inc. assigned all of its rights in the international and national applications to Human RT in January 2001 (Exhibit B). A change of Applicant was filed with the International Bureau of WIPO on January 26, 2001 along with a Power of Attorney from Human RT appointing Dr. jur. Eva Somfai as Agent for Applicant (Exhibit C).

On January 26, 2001 Dr. Somfai (Human RT's foreign patent counsel) requested Kenyon & Kenyon (Human RT's U. S. patent counsel) to enter the national phase in the United States of PCT/US99/17179. Copies of January 26, 2001 order letter and Information Sheet for New Patent Application are attached (Exhibit D).

On January 26, 2001, Dr. Eva Somfai filed with the International Bureau a Rule 92bis letter requesting the addition of inventors, Lajos HEGEDUS, Krisztina KREMPELS, Krisztina PAAL and Gabor PETHO (Exhibit E).

On April 26, 2001 Kenyon & Kenyon sent a letter to Dr. Somfai sending copies of the application as filed, Declaration and Assignment forms for signing by the inventors three (3) originally-named inventors and a Power of Attorney form for signing by the Assignee, Human RT. Reminder letters were sent to Dr. Somfai on June 29, 2001 and August 30, 2001.

Despite many attempts, Kenyon & Kenyon was unable to contact the three inventors, as did the foreign patent counsel. On July 9, 2003, letters were sent by Kenyon & Kenyon to the three originally-named inventors by Registered Mail, Return Receipt Requested to their last known addresses as follows:

Tenshuk A. Kadima  
7 Woodington Bay  
Winnipeg, Manitoba, Canada R3P 1M6

Howard A. Kaplan  
18 Hillhouse Road  
Winnipeg, Manitoba, Canada R2V 2V9

Robert C. Tuttle  
782 Allegheny Drive  
Winnipeg, Manitoba, Canada R3T 5L2

The letters included copies of the application as filed and a Declaration form for signing and returning to Kenyon & Kenyon. Copies of the letters are attached (Exhibit F).

The letter addressed to Mr. Kadima was returned as unclaimed (Exhibit G).

The letter addressed to Mr. Tuttle was returned as "address incomplete" by the Canadian Postal Service (Exhibit H). The address used was the only address listed in the International Publication Number WO 00/06152 of PCT/US99/17179. We attempted to obtain address for the inventors through Lexis and Westlaw, but without success (Exhibit I).

We learned that one of the inventors, Dr. Howard Kaplan, was deceased. We contacted the attorney for the heir of Dr. Kaplan, Mr. Randall Gray of Pitblado Buchwald Asper, Manitoba, Canada. Mr. Gray referred us to Mr. Robert A. Watchman of that firm to resolve the matter. Mr. Gray, after discussing the matter with Mr. Kaplan's heir, Ms. Carole Grad, advised us by letter dated March 22, 2004 (Exhibit J) that Ms. Grad cannot sign the Declaration as worded, because she cannot declare that she has reviewed and understands the content of the specification, including the claims, among other things. (As the sister of the inventor, she does not have the scientific background to understand the invention.)

Accordingly, despite our diligent efforts to contact the originally-named inventors to obtain a signed Declaration, we were unable to obtain signatures from the three inventors. We therefore respectfully petition the Commissioner under 37 C.F.R. §§1.47(b) and 1.42 to make application for patent on behalf of and as agent for all the inventors and Human RT, assignee of PCT/US99/17179.

In view of the foregoing, Applicants respectfully request that this Petition be granted under these specific facts.

Applicants also respectfully request that the following four (4) additional inventors be added to this application:

After resolution of the 37 C.F.R. §§1.47(b) and 1.42 issues, Applicants will submit formal documents to add the above-mentioned additional four inventors to this application. These inventors (Lajos HEGEDUS, Krisztina KREMPELS, Krisztina PAAL and Gabor PETHO) have been previously included in the PCT (see Exhibit E).

A copy of the Notice to File Missing Parts of Application is also enclosed.

Applicants respectfully request a four-month extension of time to respond to the Notice to File Missing Parts of Nonprovisional Application, Filing Date Granted, for which a response period expiring on January 26, 2004 was set. The extended period expires on May 26, 2004.

The Commissioner is hereby authorized to charge payment of the following fees to the deposit account of Kenyon & Kenyon, No. 11-0600:

- 1) Basic Filing Fee of \$770.00; --
- 2) Additional claims fee of \$1,106.00;
- 3) 37 C.F.R. §1.17(i) petition fee of \$130.00;
- 4) 37 C.F.R. § 1.136(a) extension fee of \$1,480.00; and
- 5) 37 C.F.R. § 1.116(e) surcharge of \$130.00.

The Commissioner is also authorized to charge any additional fees and credit any overpayment in connection with this communication to the deposit account of Kenyon & Kenyon, No. 11-0600. A copy of this communication is enclosed herewith for charging purposes.

Respectfully submitted,

Dated: 5/19/04

By Siu K. Lo  
Siu K. Lo  
Reg. No. 46,877

KENYON & KENYON  
One Broadway  
New York, New York 10004  
Tel: (212) 425-7200  
Fax: (212) 425-5288

CUSTOMER NUMBER 26646

2month

0007350

TLS

figur

## PCT

~~EXHIBIT A~~WORLD INTELLECTUAL PROPERTY ORGANIZATION  
International Bureau

P-0112

## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 :  A61K 31/337, 47/48, 47/42	A1	(11) International Publication Number: WO 00/06152  (43) International Publication Date: 10 February 2000 (10.02.00)
(21) International Application Number: PCT/US99/17179.		(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).
(22) International Filing Date: 29 July 1999 (29.07.99)		
(30) Priority Data: 60/094,687 30 July 1998 (30.07.98) US		
(71) Applicant (for all designated States except US): NOVOPHARM BIOTECH, INC. [CA/CA]; 30 Novopharm Court, Toronto, Ontario M1B 2K9 (CA).		
(72) Inventors; and		
(75) Inventors/Applicants (for US only): KADIMA, Tenshuk, A. [CA/CA]; 7 Woodington Bay, Winnipeg, Manitoba R3P 1M6 (CA). KAPLAN, Howard, A. [CA/CA]; 18 Hillhouse Road, Winnipeg, Manitoba R2V 2V9 (CA). TUTTLE, Robert, C. [US/CA]; 782 Allegheny Drive, Winnipeg, Manitoba R3T 5L2 (CA).		
(74) Agents: WU, Frank et al.; Morrison & Foerster LLP, 755 Page Mill Road, Palo Alto, CA 94304-1018 (US).		
(54) Title: PHARMACEUTICALLY ACCEPTABLE COMPOSITION COMPRISING AN AQUEOUS SOLUTION OF PACLITAXEL AND ALBUMIN		
(57) Abstract		
		<p>An optically clear, pharmaceutically acceptable aqueous composition comprising paclitaxel or a derivative thereof, serum albumin and a pharmaceutically acceptable vehicle, wherein the composition comprises no more than 10 % organic solvent and has a pH of about 3.0 to about 4.8, is described. The serum albumin can be fatted or defatted, and the composition can optionally be lyophilized or optionally lyophilized and reconstituted. At least 70 % of the paclitaxel is bound to serum albumin, the ratio of paclitaxel to albumin is at least about 1:5, and the concentration of paclitaxel is at least about 25 µg/ml. Methods of making and using this composition are also provided.</p>



Patrick J. Birde  
Direct 212.908.6452  
pbirde@kenyon.com

One Broadway  
New York, NY 10004-1050  
212.425.7200  
Fax 212.425.5288

## EXHIBIT F

July 9, 2003

**VIA REGISTERED MAIL -**  
**Return Receipt Requested**

Mr. Tenshuk A. Kadima  
7 Woodington Bay  
Winnipeg, Manitoba  
Canada R3P 1M6

Re: U. S. Patent Application Serial No. 10/293,426  
PHARMACEUTICALLY ACCEPTABLE COMPOSITION  
COMPRISING AN AQUEOUS SOLUTION OF  
PACLITAXEL AND ALBUMIN  
Our Ref: 11701/46003

Dear Mr. Kadima:

We are contacting you on behalf of our client, Human RT.

As you may recall, Human RT purchased the rights to the above-referenced invention from Novopharm Biotech Inc. A patent application has been filed in the United States and has been assigned Serial No. 10/293,426. In order to complete the filing requirements for the application, we are now required to file a Declaration signed by all the inventors. A Declaration form is enclosed along with a copy of the application as filed in the United States Patent Office for your review.

Please sign and date the Declaration form where indicated and return the signed form to us as soon as possible. A postage paid DHL return envelope is enclosed for your convenience in returning the form.

If we do not hear from you within two (2) weeks from the date of this letter, we will assume you are unwilling to sign the form and will proceed accordingly.

Please feel free to contact myself (212-908-6452) or Mary Werner (212-908-6183) or in writing if you have any questions in this matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Patrick J. Birde".

Patrick J. Birde

Enclosures

cc: Dr. Eva Somfai (w/o enc.)  
Steven J. Lee, Esq. (w/o enc.)

New York Washington, DC Silicon Valley [www.kenyon.com](http://www.kenyon.com)



Patrick J. Birde  
Direct 212.908.6452  
pbirde@kenyon.com

One Broadway  
New York, NY 10004-1050  
212.425.7200  
Fax 212.425.5288

July 9, 2003

**VIA REGISTERED MAIL -**  
**Return Receipt Requested**

Mr. Robert C. Tuttle  
782 Allegheny Drive  
Winnipeg, Manitoba  
CANADA R3T 5L2

Re: U. S. Patent Application Serial No. 10/293,426  
**PHARMACEUTICALLY ACCEPTABLE COMPOSITION**  
**COMPRISING AN AQUEOUS SOLUTION OF**  
**PACLITAXEL AND ALBUMIN**  
Our Ref: 11701/ 46003

Dear Mr. Tuttle:

We are contacting you on behalf of our client, Human RT.

As you may recall, Human RT purchased the rights to the above-referenced invention from Novopharm Biotech Inc. A patent application has been filed in the United States and has been assigned Serial No. 10/293,426. In order to complete the filing requirements for the application, we are now required to file a Declaration signed by all the inventors. A Declaration form is enclosed along with a copy of the application as filed in the United States Patent Office for your review.

Please sign and date the Declaration form where indicated and return the signed form to us as soon as possible. A postage paid DHL return envelope is enclosed for your convenience in returning the form.

If we do not hear from you within two (2) weeks from the date of this letter, we will assume you are unwilling to sign the form and will proceed accordingly.

Please feel free to contact myself (212-908-6452) or Mary Werner (212-908-6183) or in writing if you have any questions in this matter.

Sincerely,

  
Patrick J. Birde

Enclosures

cc: Dr. Eva Somfai (w/o enc.)  
Steven J. Lee, Esq. (w/o enc.)

New York Washington, DC Silicon Valley [www.kenyon.com](http://www.kenyon.com) 608453



Patrick J. Birde  
Direct 212.908.6452  
pbirde@kenyon.com

One Broadway  
New York, NY 10004-1050  
212.425.7200  
Fax 212.425.5288

July 9, 2003

**VIA REGISTERED MAIL -**  
**Return Receipt Requested**

Mr. Howard A. Kaplan  
18 Hillhouse Road  
Winnipeg, Manitoba  
CANADA R2V 2V9

Re: U. S. Patent Application Serial No. 10/293,426  
PHARMACEUTICALLY ACCEPTABLE COMPOSITION  
COMPRISING AN AQUEOUS SOLUTION OF  
PACLITAXEL AND ALBUMIN  
Our Ref: 11701/ 46003

Dear Mr. Kaplan:

We are contacting you on behalf of our client, Human RT.

As you may recall, Human RT purchased the rights to the above-referenced invention from Novopharm Biotech Inc. A patent application has been filed in the United States and has been assigned Serial No. 10/293,426. In order to complete the filing requirements for the application, we are now required to file a Declaration signed by all the inventors. A Declaration form is enclosed along with a copy of the application as filed in the United States Patent Office for your review.

Please sign and date the Declaration form where indicated and return the signed form to us as soon as possible. A postage paid DHL return envelope is enclosed for your convenience in returning the form.

If we do not hear from you within two (2) weeks from the date of this letter, we will assume you are unwilling to sign the form and will proceed accordingly.

Please feel free to contact myself (212-908-6452) or Mary Werner (212-908-6183) or in writing if you have any questions in this matter.

Sincerely,  
  
Patrick J. Birde

Enclosures

cc: Dr. Eva Somfai (w/o enc.)  
Steven J. Lee, Esq. (w/o enc.)

New York Washington, DC Silicon Valley [www.kenyon.com](http://www.kenyon.com)

# EXHIBIT B

## ASSIGNMENT

We, the undersigned, hereby agree

Attn: Dr. László Nagy  
30, Nemeskörút 1  
Budapest, Hungary

declare to have no objection our exclusive rights related to  
patent application/patents mentioned below on

HUMAN RT.  
Temesvár M.u.02.  
H-9100 Godollo, Hungary

We also agree that this assignment is registered in the  
register of all international or national patent  
authorities.

### Date of the patent application:

Number: PCT/HU99/17179  
Title: "Biolabonattyly Acceptable Composition  
Comprising an Aqueous Solution of Facitaxel  
and Albenox"  
Priority: 30/09/1997 30. July 1998

### For the Assignor:

Date:  
Budapest, January 2001

### For the Assignee:

Date:  
Godollo, January 2001

Signed by:

Capacity:

MICHAEL A. BYRNE  
CHIEF FINANCIAL OFFICER

Signed by:  
Lajos Nagy

  
Capacity:  
General manager

P-0112

HUMAN  
SERUM PRODUCTION AND  
MEDICINE MANUFACTURING  
COMPANY LIMITED BY SHARES  
Temesvár M.u. 82.  
Godollo, Hungary  
2100

Werner, Mary

*EXHIBIT I*

**From:** Werner, Mary  
**Sent:** Friday, August 01, 2003 2:03 PM  
**To:** Butler, Timothy  
**Subject:** RE: 11701/46001 - for Tuesday

Thanks, Tim.

—Original Message—

**From:** Butler, Timothy  
**Sent:** Friday, August 01, 2003 2:01 PM  
**To:** Werner, Mary  
**Subject:** RE: 11701/46001 - for Tuesday

Mary

It turns out that they can only obtain this information for people in the US. I'm going to hold on to this and try Westlaw next week. This was the answer which I received from your Lexis representative.

—Original Message—

**From:** Werner, Mary  
**Sent:** Thursday, July 24, 2003 6:36 PM  
**To:** Butler, Timothy  
**Subject:** 11701/46001 - for Tuesday

Tim,

These are the inventors in Canada for whom we need updated addresses:

KADIMA, Tenshuk, A., 7 Woodington Bay, Winnipeg, Manitoba R3P 1M6, CA 02

KAPLAN, Howard, A., 18 Hillhouse Road, Winnipeg, Manitoba R2V 2V9, CA 03

TUTTLE, Robert, C., 782 Allegheny Drive, Winnipeg, Manitoba R3T 5L2 / CA 04

Thanks.

Mary

**Werner, Mary**

---

**From:** Butler, Timothy  
**Sent:** Wednesday, August 06, 2003 7:22 PM  
**To:** Werner, Mary  
**Subject:** RE: 11701/46001 - for Tuesday

Mary

I tryed again with West law . sorry no results

—Original Message—

**From:** Werner, Mary  
**Sent:** Thursday, July 24, 2003 6:36 PM  
**To:** Butler, Timothy  
**Subject:** 11701/46001 - for Tuesday

Tim,

These are the inventors in Canada for whom we need updated addresses:

KADIMA, Tenshuk, A., 7 Woodington Bay, Winnipeg, Manitoba R3P 1M6, CA 02

KAPLAN, Howard, A., 18 Hillhouse Road, Winnipeg, Manitoba R2V 2V9, CA 03

TUTTLE, Robert, C., 782 Allegheny Drive, Winnipeg, Manitoba R3T 5L2 / CA 04

Thanks.

Mary

08:08AM FROM-PITBLADO

204 957 0227

T-558 P.002/003 F-343

**PITBLADO**  
ARRISTERS & SOLICITORS

EXHIBIT J

2500 - 360 Main Street  
Winnipeg, Manitoba  
Canada R3C 4H6

Tel. (204) 956 0560  
Fax (204) 957 0227  
E-mail firm@pitblado.com

VIA TELECOPIER 212-425-5288

March 22, 2004

Kenyon & Kenyon  
One Broadway  
New York, NY 10004-1050

Attention: Siu K. Lo

Dear Sir:

**Re: U.S. Patent Application Serial No. 10/293,426  
Your Reference: 1662/46003**

This will acknowledge receipt of your letter dated March 11, 2004 enclosing documentation with respect to the above-noted application.

As you may recall in our telephone conversation of September 3, 2003, because of the particular wording of the inventor's declaration for the United States, the representative of Dr. Kaplan's estate cannot sign the declaration. That is, the wording requires her to declare, under threat of penalty, that she has reviewed and understands the content of the specification, including the claims, amongst other things.

We wish to emphasize that Ms. Grad does not wish to appear to be uncooperative and she is not disputing the application or your client's entitlement to the invention, it is simply that she cannot sign the declaration as worded.

In our telephone discussion, I referred to other patent applications in which the same issue arose in which the applicant proceeded on the basis that the representative "refuses" to sign the declaration, which I believe is provided for in 37 CFR 1.42.

In our September 3, 2003 telephone conversation, you indicated that you believe the rules might have provided for some variation when the documents were to be signed by a representative. However, unless there is some other wording for the declaration, the representative of Dr. Kaplan's estate will not be able to sign.

Yours very truly,

**PITBLADO**

per: *Doreen Wager*  
Robert A. Watchman  
RAW:dew

for